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510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Claire Arakaki
Philips Medical Systems
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United States
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DEC 18 2009

This summary was prepared on September 25, 2009.

2. The name of the subject device is the Philips IntelliBridge System.

3. The trade name of the device is the Philips IntelliBridge System.

4. The common usual name is data management system.

5. The Classification names are as follows:

Device Panel	Classification	ProCode	Description
General Hospital	Not classified	NSX	Software, transmission and storage, patient data
Cardiovascular	870.2300, II	MWI	Monitor, Physiological, Patient (without arrhythmia detection or alarms)
Cardiovascular	870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)

6. The modified device is substantially equivalent to the previously cleared Philips DeviceLink System.

7. The major modifications are as follows:
   - Introduction of a new multi-port module (EC40/EC80)
   - Introduction of a management console (SC50)

8. The subject device has the same intended use as the legally marketed predicate device:
   The IntelliBridge System is indicated for use in the data collection and clinical information management either directly or through networks with independent bedside devices. The IntelliBridge System is not intended for monitoring purposes nor is the device intended to control any of the clinical devices (independent bedside devices / information systems) it is connected to.

9. The subject device has the same fundamental technological characteristics as the legally marketed predicate devices.

10. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject devices with respect to the predicates. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device, the specifications of the subject device and test results showed substantial equivalence. The results demonstrate that the Philips IntelliBridge System meets all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Philips Medical Systems
c/o Claire Arakaki, Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810

DEC 18 2009

Re: K093177
Trade/Device Name: IntelliBridge System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: November 25, 2009
Received: November 27, 2009

Dear Ms. Arakaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (if known): _____K093177_____

Device Name: IntelliBridge System

The IntelliBridge System is indicated for use in the data collection and clinical information management. The IntelliBridge System is not intended for monitoring purposes nor is the device intended to control any of the clinical devices (independent bedside devices / information systems) it is connected to.

Prescription Use: ____YES_____ AND/OR over-the-counter Use: ____NO____
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K093177